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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,178	09/03/2003	Eiji Kanehira	00034CIPC/LH	4334

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/654,178	KANEHIRA ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *2-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 49-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/793,431.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received September 26, 2006, have been fully considered by the examiner. In particular, applicant's amendments have obviated the 35 USC 101 and 35 USC 112 issues. The following is a complete response to the September 26, 2006 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1, 49-56, 61-63, 65, 66 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Treat et al (6,626,901).

Claim Rejections - 35 USC § 103

Claims 1, 52, 53 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parins et al (5,908,420) in view of the teaching of Treat et al ('901).

Parins et al disclose a medical treatment instrument comprising a treatment portion (58) including a pair of grasp portions (60,62) capable of being opened and closed. A frontal operating portion (10) is arranged at the proximal end of the device to actuate the grasp portions. A heat generating portion (122,123) is provided on each grasp portion, and a cutting portion (91,92) is disposed at the grasp portions to cut tissue. Parins et al disclose the use of RF energy to deliver current to tissue, which energy causes heating of the tissue. Parins et al do not specifically teach of heating the grasping portion which is then brought into contact with the tissue as now claimed.

Treat et al disclose an analogous device for the coagulation and cutting of tissue. In particular, Treat et al teach that a device that includes forceps jaws and a cutting

element may treat tissue with heat energy by heating the jaw members, as opposed to delivering RF energy to tissue. Treat et al also teach that mechanical cutters may be used with the heat generating jaws, or that distinct energy levels may be selected to enable cutting and/or coagulation of tissue (col. 17, lines 55+).

To have provided the Parins et al device with a heat generating means to generate heat energy within the jaw members for coagulating and cutting tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Treat et al.

Claims 1 and 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornerup (6,679,882) in view of the teaching of Treat et al ('901).

Kornerup provides a forceps device with a cutting member (22). Electrical energy is provided at different energy levels to the jaw area to coagulate or cut tissue using various switching means. Again, the grasp members may be considered elongate and flat (i.e. along the grasping edge) or curved in the shape of an arc (when looking from above). Kornerup delivery RF current to heat tissue, as opposed to heating the jaw members and applying the heat to tissue.

Treat et al disclose an analogous device for the coagulation and cutting of tissue. In particular, Treat et al teach that a device that includes forceps jaws and a cutting element may treat tissue with heat energy by heating the jaw members, as opposed to delivering RF energy to tissue. Treat et al also teach that mechanical cutters may be

used with the heat generating jaws, or that distinct energy levels may be selected to enable cutting and/or coagulation of tissue (col. 17, lines 55+).

To have provided the Kornerup device with a heat generating means to generate heat energy within the jaw members for coagulating and cutting tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Treat et al.

Claims 1, 49-56 and 61-69 are rejected under 35 U.S.C. 103(a) as unpatentable over Yamauchi et al (6,273,887).

The Yamauchi et al patent has a common inventor with the instant application and discloses substantially the same device. It includes a forceps device with means to provide either a cutting or a coagulating energy level to the jaws (Figure 27). The jaws may take various configurations and includes a resin material located within the jaw members. Yamauchi et al disclose various different embodiments for the shapes of the grasping members similar to those disclosed in the instant application. Yamauchi et al also disclose the delivery of RF current, as opposed to generating heat within the jaw members.

Treat et al disclose an analogous device for the coagulation and cutting of tissue. In particular, Treat et al teach that a device that includes forceps jaws and a cutting element may treat tissue with heat energy by heating the jaw members, as opposed to delivering RF energy to tissue. Treat et al also teach that mechanical cutters may be

used with the heat generating jaws, or that distinct energy levels may be selected to enable cutting and/or coagulation of tissue (col. 17, lines 55+).

To have provided the Yamauchi et al device with a heat generating means to generate heat energy within the jaw members for coagulating and cutting tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Treat et al.

Claims 1, 49-54 and 61-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrublewski et al (6,174,309) in view of the teaching of Treat et al ('901).

Wrublewski et al disclose yet another tissue grasping and cutting device that includes a pair of grasping elements with electrical connections to provide either a coagulating or a cutting current to tissue. A plurality of switches are inherently included to provide the different energy levels (col. 2, lines 55-59). A cutting member is also provided for cutting tissue. The grasping surfaces may be elongated and flat (Figure 6C) or may have a rounded shape (Figure 6A, when looking from above) or may be curved along the length (Figure 6B). Each jaw has a differently shaped contact surface yielding different contact areas and Wrublewski et al disclose slip prevention portions (i.e. notches as seen in the cross-section views of Figures 5A and 5B) as well as non-stick coatings on the electrode (col. 2, lines 20-25). The cross sections of the Figure 5 embodiments show various contact surfaces, including rectangular, notched and

chamfered surfaces. Wrublewski et al disclose the delivery of RF current, and not specifically heating the jaw members.

Treat et al disclose an analogous device for the coagulation and cutting of tissue. In particular, Treat et al teach that a device that includes forceps jaws and a cutting element may treat tissue with heat energy by heating the jaw members, as opposed to delivering RF energy to tissue. Treat et al also teach that mechanical cutters may be used with the heat generating jaws, or that distinct energy levels may be selected to enable cutting and/or coagulation of tissue (col. 17, lines 55+).

To have provided the Wrublewski et al device with a heat generating means to generate heat energy within the jaw members for coagulating and cutting tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Treat et al.

Claims 61-65 and 67-69 are rejected under 35 U.S.C. 103(a) as being anticipated by Baker (6,113,598) in view of the teaching of Treat et al ('901).

Baker et al discloses a surgical instrument comprising a distal end portion including a pair of holding portions (30A, 30B). An operation portion (i.e. handle) is provided at the proximal end for opening and closing the holding portions, and each holding portion includes a heat generating portion (i.e. electrode) formed in a contact portion. The heat generating portions may take various shapes and have different contact areas (see Figures), and may be arcuate in cross-section (Figures 3A,3B). The body of the holding portions may be made of a flexible, heat resistant material such as

rubber (col. 13, lines 5-10). The heat generating portion may also be made of a flexible material. Figures 12A-12C show the heat generating portion (132) deforming. Baker discloses the delivery of RF energy as opposed to heating the jaw members.

Treat et al disclose an analogous device for the coagulation and cutting of tissue. In particular, Treat et al teach that a device that includes forceps jaws and a cutting element may treat tissue with heat energy by heating the jaw members, as opposed to delivering RF energy to tissue. Treat et al also teach that mechanical cutters may be used with the heat generating jaws, or that distinct energy levels may be selected to enable cutting and/or coagulation of tissue (col. 17, lines 55+).

To have provided the Baker device with a heat generating means to generate heat energy within the jaw members for coagulating and cutting tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Treat et al.

Claims 55-60 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrublewski et al ('309) and Treat et al ('901) and further in view of the teaching of Baker ('598).

The Wrublewski et al reference has been addressed previously. The Wrublewski et al jaws including a receiving member (i.e. portion of jaw that holds the electrode), but fails to disclose the particular materials used to make the receiving members (i.e. jaws).

As asserted previously, Baker discloses the use of various materials for making the jaw members to support the heating electrodes. In particular, Baker teaches the

use of flexible materials such as rubber (col. 13, lines 5-10). The examiner maintains that the use of any other well known material, including a resin or a fluoroplastic, would be deemed obvious design considerations as these materials are generally well-known and often used as support materials in RF heating devices.

To have formed the Wrublewski et al device, as modified by the teaching of Treat et al, with jaws made from any well-known material, such as rubber, to provide a heat resistant support for the electrodes would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Baker.

Claims 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al ('887) and Treat et al ('901) and further in view of the teaching of Baker ('598).

The Yamauchi et al device has been addressed previously. While Yamauchi et al disclose various embodiments for the jaws, there is no disclosure that the jaw members include a receiving member made from rubber, gel or fluoroplastic as set forth in claims 57-59.

As asserted previously, Baker discloses the use of various materials for making the jaw members to support the heating electrodes. In particular, Baker teaches the use of flexible materials such as rubber (col. 13, lines 5-10). The examiner maintains that the use of any other well known material, including a resin, gel or a fluoroplastic, would be deemed obvious design considerations as these materials are generally well-known and often used as support materials in RF heating devices.

To have formed the Yamauchi et al jaws, as modified by the teaching of Treat et al, from any well-known material, such as rubber, to provide a heat resistant support for the electrodes would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Baker.

Claims 55-60 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treat et al ('901) and further in view of the teaching of Baker ('598).

The Treat et al reference has been addressed previously. The Treat et al jaws include a receiving member (i.e. portion of jaw that holds the electrode), but fail to disclose the particular materials used to make the receiving members (i.e. jaws).

As asserted previously, Baker discloses the use of various materials for making the jaw members to support the heating electrodes. In particular, Baker teaches the use of flexible materials such as rubber (col. 13, lines 5-10). The examiner maintains that the use of any other well known material, including a resin or a fluoroplastic, would be deemed obvious design considerations as these materials are generally well-known and often used as support materials in RF heating devices.

To have formed the Treat et al jaws from any well-known material, such as rubber, to provide a heat resistant support for the electrodes would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Baker.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Koch et al (4,685,459), Herzon (6,533,778), Carr et al (5,792,137) and Karasawa et al (7,025,763) all disclose forceps devices that cause heating of the jaw member to treat tissue.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 14, 2006